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10/733,064	12/11/2003	Alexander Sulakvelidze	62610.000044	7824

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EXAMINER	
KINSEY WHITE, NICOLE ERIN	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,064	SULAKVELIDZE ET AL.	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-45,88-96 and 98-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *43-45,88-96,98-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/13/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-45, 88-89, and 98-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merril et al. (U.S. Patent No. 5,811,093) in view of Byrd et al. (Applied Poultry Science, 1998, 7:75-80), Taylor et al. (U.S. Patent No. 2,851,006) and Berchieri et al. (Res. Microbiol., 1991, 142:541-549) and as evidenced by Holzman (Genetic Engineering News, 1998, 18(18)).

The claims are drawn to a method for poultry processing sanitation with at least one bacteriophage, comprising: applying the at least one bacteriophage to at least one

freshly-hatched bird before transferring said at least one freshly-hatched bird to a chicken house.

Merril et al. discloses topically treating animals (e.g., man, domestic pets, livestock, pisciculture, and animals in zoos and aquatic parks) with a composition comprising bacteriophage to kill bacteria (see col. 9, line 42 to col. 11, line 3). It is common knowledge that chickens, including newly hatched chicks, are livestock (The Cambridge Dictionary of American English defines livestock as "animals kept on a farm, such as cows, sheep, chickens, and pigs." Further, Holzman, quoting Dr. Alexander Sulakvelidze, a current inventor, states that "Intralytix plans to target pathogens that plague livestock, such as Salmonella in meat, poultry and eggs.") The phage formulations are for the prevention and treatment of bacterial infection in humans and animals, and the routes of administration include, oral, aerosol or other device for delivery to the lungs, nasal spray, intravenous, intramuscular, intraperitoneal, intrathecal, vaginal, rectal, and topical (see col. 10, lines 58-62).

Merril et al. does not disclose the use of a cocktail of bacteriophage or applying the bacteriophage specifically to a freshly-hatched bird.

Byrd et al. teaches that boiler breeder flocks and hatcheries are reservoirs of salmonellae and potential sources of *Salmonella* infection for day-old chicks. Byrd et al. further teaches that *Salmonella* is shed into the environment to contaminate it and to colonize other chicks and that *Salmonella* contamination occurs in essentially all phases of broiler production (see Abstract and Introduction).

Berchieri et al. teaches that chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching (see page 142, Introduction).

Taylor et al. discloses using cocktails of bacteriophage to assure the destruction of all possible species of bacteria, namely *Salmonella* (col. 2, lines 25-44). Taylor et al. also teaches that eggs are infected/contaminated with *Salmonella*.

Holzman discloses using bacteriophage to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs as a way of potentially clearing the poultry yards of *S. enteriditis*. Holzman states that "[u]p to 75% of human cases are acquired from meat, poultry or eggs, and up to 25% of broiler chickens and 18% of turkey carry that organism." (see page 48 of Holzman).

In summary, the cited references teach that i) poultry, including chicks, and eggs are infected with Salmonella, ii) poultry, including chicks, live in contaminated environments, iii) boiler breeder flocks and hatcheries are reservoirs of salmonellae and potential sources of *Salmonella* infection for day-old chicks, iv) *Salmonella* is shed into the environment to contaminate it and to colonize other chicks and that *Salmonella* contamination occurs in essentially all phases of broiler production, v) chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching, vi) bacteriophage can be used to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs as a way of potentially clearing the poultry yards of bacteria, and vii) eggs are infected/contaminated with *Salmonella*. Thus, the references teach that chicks, e.g., freshly hatched chicks, are contaminated and infected with bacteria, namely *Salmonella*.

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Merril et al. and use a cocktail of bacteriophage to topically treat contaminated livestock. One would have been motivated to do so given the suggestion by Taylor et al. that cocktails of phages should be used to assure the destruction of all possible species of bacteria. There would have been a reasonable expectation of success given the knowledge that phages kill bacteria and also given the knowledge that more than one strain, serotype or species of bacteria can contaminate/infect an animal as evidenced by Berchieri et al.

It would have also been obvious to one of ordinary skill in the art to use the method taught by Merril et al. to topically apply the bacteriophage composition to chickens, including freshly-hatched chicks, and eggs. One would have been motivated to do so, given the suggestion by Holzman to use phages to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs, and *E, coli 0157*, and given the teachings of Berchieri et al. (chicks are infected within a few hours of hatching) and Byrd et al. (*Salmonella* is shed by contaminated chicks into the environment to contaminate it and to colonize other chicks and that *Salmonella* contamination occurs in essentially all phases of broiler production). There would have been a reasonable expectation of successfully disinfecting a freshly-hatched chick because i) chicks are contaminated and infected with bacteria soon after hatching and ii) bacteriophage are known to kill bacteria.

The recitation " a method for poultry processing sanitation" is an intended use of the process. A recitation of intended use of the claimed invention must result in a

structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitations. See In re Casey, 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458,459 (CCPA 1963). Here, the combined teachings of Merril et al., Berchieri et al., Byrd et al., Holzman and Taylor et al. (administering a phage cocktail topically to livestock including chickens) is capable of performing the intended use of the instant claims (sanitizing poultry).

Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

In the reply and Declaration dated May 13, 2008, applicants argue that Merrill et al. is directed to phage therapy in infected animals, and not prophylaxis of uninfected animals and that freshly hatched chicks are not infected, i.e., the gastrointestinal tract is not colonized. Applicants' arguments and Declaration have been fully considered, but not found persuasive.

Berchieri et al. teaches that chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching. In addition, the combined teachings of the cited references establish that i) poultry, including chicks, are infected with Salmonella, ii) poultry, including chicks, live in contaminated environments, iii) boiler breeder flocks and hatcheries are reservoirs of salmonellae and potential sources of *Salmonella* infection for day-old chicks, iv) *Salmonella* is shed into the environment to contaminate

it and to colonize other chicks and that *Salmonella* contamination occurs in essentially all phases of broiler production, v) chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching, vi) bacteriophage can be used to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs as a way of potentially clearing the poultry yards of bacteria, and vii) eggs are infected/contaminated with *Salmonella*. Thus, the references, in combination, teach that chicks, e.g., freshly hatched chicks, are contaminated and infected with bacteria, namely *Salmonella*.

Although it may be possible that a freshly hatched bird is uninfected, i.e., the gut is not colonized, this does not negate the fact that the birds are hatched into and live in contaminated environments, as outlined above, and that Merrill et al. teaches the topical administration of phage to livestock to kill bacteria.

Applicants' reply and Declaration discuss and attack each reference singly, and not the combined teachings of the references as outlined above.

Claims 94-96 and 102-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merril et al. (U.S. Patent No. 5,811,093) as applied to claims 43-45, 88-89, and 98-101 above, and further in view of Day et al. (U.S. Patent No. 4,851,240), Taylor et al. (U.S. Patent No. 2,851,006), Byrd et al. (Applied Poultry Science, 1998, 7:75-80) and Berchieri et al. (Res. Microbiol., 1991, 142:541-549).

The claims are drawn to a method for poultry processing sanitation with at least one bacteriophage, comprising: applying the at least one bacteriophage to at least one

freshly-hatched bird before transferring said at least one freshly-hatched bird to a chicken house, wherein drinking water and food comprising at least one bacteriophage is provided to the bird.

The teachings of Merril et al., Byrd et al. and Berchieri et al. are outlined above.

Merril et al. further teaches that the phage formulations can be administered orally to humans and livestock for the prevention and treatment of bacterial infections (see col. 10, lines 58-62). Merril et al. does not disclose orally administering the phage composition via food or drinking water.

Berchieri et al. further teaches that chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching (see page 142, Introduction). Berchieri et al. further suggests that reducing the numbers of *Salmonella* in the gut might reduce not only the associated risk of food-poisoning, but also mortality in the chickens. Furthermore, Berchieri et al. demonstrated that chickens orally inoculated with *S. typhimurium* and then inoculated with a phage composition showed reduced mortality (see Experimental Plan, p. 543 and p. 545).

Byrd et al. further teaches that day-of-hatch chicks can become colonized by exposure to 100 times fewer *Salmonella* organisms than chicks challenged at Day 3 resulting in chicks that excrete large numbers of salmonellae into the environment, so that uncolonized chicks become infected during the first week of growout (see page 76).

Day et al. discloses liquid preparation of at least two varieties of bacteriophage, which may be a formulation of phage in food or drinking water, for administering to

livestock (see col. 5, line 41 to col. 6, line 5). The phage formulations are for the prevention and treatment of microbial infestations.

Taylor et al. teaches using a cocktail of different phages (col. 2, lines 25-44) to treat fertilized eggs contaminated with *Salmonella* (cocktails of phages should be used to assure the destruction of all possible species of bacteria, namely Salmonella).

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Merril et al. to orally administer a cocktail of bacteriophage as taught by Day et al. and Taylor et al. to livestock (e.g., chickens and freshly-hatched chicks) via drinking water and/or feed. One would have been motivated to do so, given the suggestion by Berchieri et al. that reducing the numbers of *Salmonella* in the gut might reduce not only the associated risk of food-poisoning, but also mortality in the chickens and given the teachings of Berchieri et al. (chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching) and Byrd et al. (chicks can become colonized with 100 times fewer *Salmonella* organisms and excrete large numbers of salmonellae that can infected uncolonized chicks). There would have been a reasonable expectation of success given the fact that Berchieri et al. successfully inoculated *Salmonella* infected chicks via the oral route and observed a decrease in mortality when phage were administered and given the fact that Day et al. used phage-treated feed and drinking water to treat other livestock with bacterial infections.

The recitation " a method of poultry processing sanitation" is an intended use of the process. A recitation of intended use of the claimed invention must result in a structural difference (or, in the case of process claims, manipulative difference) between

the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitations. See In re Casey, 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458,459 (CCPA 1963). Here, the combined teachings of Merril et al., Berchieri et al., Byrd et al., and Day et al. (administering drinking water or food containing a mixture of phage to livestock (e.g., chickens) is capable of performing the intended use of the instant claims (sanitizing poultry).

Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

In the reply and Declaration dated May 13, 2008, applicants argue that the combination of Merrill et al., Byrd et al., Berchieri et al. and Taylor et al. does not teach the claimed invention. Applicants further argue that Day et al. is directed to treating ruminant livestock with phage and not poultry. Applicants' arguments and Declaration have been fully considered, but not found persuasive.

As summarized above, the cited references teach that i) poultry, including chicks, and eggs are infected with Salmonella, ii) poultry, including chicks, live in contaminated environments, iii) boiler breeder flocks and hatcheries are reservoirs of salmonellae and potential sources of *Salmonella* infection for day-old chicks, iv) *Salmonella* is shed into the environment to contaminate it and to colonize other chicks and that *Salmonella* contamination occurs in essentially all phases of broiler production, v) chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching, vi)

bacteriophage can be used to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs as a way of potentially clearing the poultry yards of bacteria, and vii) eggs are infected/contaminated with *Salmonella*. Thus, the references teach that chicks, e.g., freshly hatched chicks, are their environment are contaminated and infected with bacteria, namely *Salmonella*.

Day et al. discloses liquid preparation of at least two varieties of bacteriophage, which may be a formulation of phage in food or drinking water, for administering to livestock (see col. 5, line 41 to col. 6, line 5). The phage formulations are for the prevention and treatment of microbial infestations. Thus, given the highly contaminated environment that chicken lives in and given the fact that chickens and eggs are reservoirs of salmonellae and potential sources of *Salmonella* infection, one of ordinary skill in the art is lead to use the treatment method of Day et al. (i.e., treat gastrointestinal bacterial infections with phage in water or food) to treat other types of livestock, e.g., chickens, with a reasonable expectation of success.

Claims 90-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. Patent No. 2,851,006) in view of Cox et al. (Journal of Applied Poultry Research, 1994, 3:234-237) and Holzman (Genetic Engineering News, 1998, 18(18)).

Taylor et al. discloses submerging fertilized eggs infected with *Salmonella* into fluid containing bacteriophages to disinfect the eggs (see entire document). Example I demonstrates the infection of eggs by submerging the eggs in a chilled culture of *Salmonella chittagong* for 10 minutes and then submerging the infected eggs in a

polyvalent Salmonella phage containing liquid for 10 minutes. Clearly, bacteria on the egg will be killed by the phage. Taylor et al. also discloses using a cocktail of different phages (col. 2, lines 25-44).

Taylor et al. does not teach spraying the phage onto the surface of the egg.

Cox et al. teaches that hatching eggs leaving the breeder house usually carry many bacteria: on the shell surface as well as beneath the shell and/or shell membranes. Cox et al. further discloses a spray-sanitizing machine to clean and disinfect eggs using chemical disinfectants.

Holzman discloses using bacteriophage to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs as a way of potentially clearing the poultry yards of *S. enteriditis*. Holzman states that "[u]p to 75% of human cases are acquired from meat, poultry or eggs, and up to 25% of broiler chickens and 18% of turkey carry that organism." (see page 48 of Holzman).

It would have been obvious to one of ordinary skill in the art to modify the method taught by Taylor et al. to disinfect contaminated/infected eggs by spraying bacteriophage instead of dipping the eggs into a bacteriophage bath. One would have been motivated to do so given the suggestion by Holzman to use phages to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs, and *E, coli 0157* and given the teachings of Cox et al. (spraying eggs with a disinfectant reduces the number of bacteria on eggs). One of ordinary skill in the art would reasonably expect that spraying bacteriophage on eggs would successfully disinfect the eggs given the fact that spraying is an efficient method of applying a disinfectant to eggs

as taught by Cox et al. and given the fact that Taylor et al. successfully used a phage composition to disinfect contaminated/infected eggs.

It also would have been obvious to one of ordinary skill in the art to modify the method taught by Cox et al. to disinfect contaminated/infected eggs by spraying bacteriophage instead of a chemical. One would have been motivated to do so given the suggestion by Holzman to use phages to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs, and *E, coli 0157* and given the teachings of Cox et al. (spraying eggs with a disinfectant reduces the number of bacteria on eggs). One of ordinary skill in the art would reasonably expect that spraying bacteriophage on eggs would successfully disinfect the eggs given the fact that spraying is an efficient method of applying a disinfectant to eggs as taught by Cox et al. and given the fact that Taylor et al. successfully used a phage composition to disinfect contaminated/infected eggs.

Further, it would have been obvious for one of ordinary skill in the art to substitute one method of applying phage to the surface of a contaminated egg for another method and the result would have been predictable, i.e., killing bacteria.

As for where the spraying takes place (hatchery vs. elsewhere), it is well within the purview of one of ordinary skill in the art to determine when and where disinfecting should take place. One of ordinary skill in the art is well aware of when contamination takes place as well as where contamination occurs in poultry houses (see previously cited references).

The recitation " a method of poultry processing sanitation" is an intended use of the process. A recitation of intended use of the claimed invention must result in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitations. See In re Casey, 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458,459 (CCPA 1963). Here, the combined teachings of Merril et al., Berchieri et al., Byrd et al., and Day et al. (administering drinking water or food containing a mixture of phage to livestock (e.g., chickens) is capable of performing the intended use of the instant claims (sanitizing poultry).

Therefore, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

In the reply and Declaration dated May 13, 2008, applicants argue that Taylor et al. and Cox et al. relate to sanitizing an egg shortly after it is laid and not just before hatch. Applicants' arguments and Declaration have been fully considered, but not found persuasive.

As stated above, it would have been obvious to one of ordinary skill in the art to modify the method taught by Taylor et al. to disinfect contaminated/infected eggs by spraying bacteriophage instead of dipping the eggs into a bacteriophage bath.

In addition, it would have been obvious to one of ordinary skill in the art to modify the method taught by Cox et al. to disinfect contaminated/infected eggs by spraying

bacteriophage instead of a chemical given the suggestion by Holzman to use phages to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs. One of ordinary skill in the art would reasonably expect that spraying bacteriophage on eggs would successfully disinfect the eggs given the fact that spraying is an efficient method of applying a disinfectant to eggs as taught by Cox et al.

Furthermore, it would have been obvious for one of ordinary skill in the art to substitute one method of applying phage to the surface of a contaminated egg for another and the result would have been predictable, i.e., killing bacteria.

One of ordinary skill in the art is well aware of when contamination takes place as well as where contamination occurs in poultry houses (see previously cited references). Therefore, it is well within the purview of one of ordinary skill in the art to determine when and where disinfecting via bacteriophage should take place (hatchery vs. elsewhere).

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648